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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,504	01/03/2002	Daryll A. Emery	293.00020101	5492

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,504	EMERY ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-21 and 30-71* is/are pending in the application.

4a) Of the above claim(s) *9-21 and 39-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9-21 and 39-71* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed October 20, 2003 is acknowledged and has been entered. Claims 1-8 and 22-29 have been canceled. Claims 30 and 37 have been amended. Claims 30 and 31-38 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those discussed below.

2. This application contains claims 9-21 and 39-71 drawn to an invention nonelected or species nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example p. 14 of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

This objection is maintained for the reasons as set forth above. The amendment to the specification filed October 20, 2003 is not persuasive. Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not

included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >" and http:// followed by a URL address. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. This requirement does not apply to electronic documents listed on forms PTO-892 and PTO-1449 where the electronic document is identified by reference to a URL. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding incorporation by reference. Where the hyperlinks and/or other forms of browser-executable codes are part of applicant's invention and it is necessary to have them included in the patent application in order to comply with the requirements of 35 U.S.C. 112, first paragraph, and applicant does not intend to have these hyperlinks be active links, examiners

should not object to these hyperlinks. The Office will disable these hyperlinks when preparing the text to be loaded onto the USPTO web database. Note that nucleotide and/or amino acid sequence data placed between the symbols "< >" are not considered to be hyperlinks and/or browser-executable code and therefore should not be objected to as being an improper incorporation by reference (see 37 CFR 1.821 –1.825).

5. The information disclosure statement filed June 30, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The Examiner will consider references that have not been initialed if a copy of the references is provided along with the response to this Office Action.

The IDS filed October 20, 2003 has been considered, signed and a copy is being mailed with this Office Action.

6. Claims 30 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Emery et al WO 95/21627 in light of Lumsden et al (Am. J. Vet. Res., 1991, 52/11:1784-1787).

The claims are directed to a method for reducing fecal shedding of a microbe in an animal's intestinal tract, the method comprising administering to an animal (avian, bovine, caprine, porcine or ovine) a composition comprising at least two siderophore receptor proteins, SRPs, (MW of 60-100 kD) from a gram negative

microbe, at least two porins (MW of 30-43 kD) from a gram-negative microbe, LPS at a concentration of no greater than 10.0 EU/ml and a pharmaceutically acceptable carrier.

Emery et al discloses a vaccine for immunizing poultry (i.e. avian) and other animals against infection by gram-negative bacteria and that the vaccine comprises isolated SRPs from gram-negative bacteria, isolated porins from gram-negative bacteria and a physiologically acceptable carrier (abstract; p. 2; p. 47;p. 7). Emery et al discloses that the SRPs have a molecular weight of 72-96 kD (p. 3; pp. 8-10). Emery et al also discloses that the composition comprises isolated porins from gram-negative bacteria having a molecular weight of 34-38 kD (p. 14). Emery et al set forth various gram-negative bacteria suitable for use in obtaining SRPs (p. 17).

Lumsden et al is cited to show that animals vaccinated with vaccines comprising gram-negative bacteria (i.e. *Salmonella spp.*) shed Salmonella less frequently than nonvaccinated control animals (summary). The vaccine prevented fecal shedding of microbes (p. 1784).

The prior art of Emery et al appears to disclose the claimed method of administering the claimed composition (SRPs, porins and physiologically acceptable carrier) to an animal. Although the prior art is silent with regard to LPS to claim recites that the composition has a concentration no greater that 10 EU/ml, therefore a composition that has no LPS would meet that limitation. Further, with regard to the recitation of "for reducing fecal shedding of a microbe in an animal's intestinal tract", this is viewed as a recitation of the intended use. The recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In light of Lumsden it would appear that the vaccine composition of Emery et al would be useful to reduce fecal shedding of a microbe.

Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 30 and 31-38 under 35 U.S.C. § 102(b) as anticipated by Emery et al WO 95/21267 in light of Lumsden et al (Am. J. Vet. Res., 1991, 52/11:1784-1787) is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 30 and 34-38 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed October 20, 2003, have been fully considered but they are not deemed to be persuasive.

Applicants Emery et al do not teach that the compositions that were administered to animals had a concentration of LPS no greater than about 10.0 EU/ml and that it appears that this rejection is based on the doctrine of inherency. However, the recitation of "LPS at a concentration of no greater that about 10.0 EU/ml" is interpreted broadly to mean that the composition has a concentration

range of no LPS to about 10.0 EU/ml. Therefore a reference that is silent with regard to LPS would meet the limitation of the claimed composition. Further, the specification indicates that the composition should have low concentrations of LPS or undetectable concentrations (p. 14).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al WO 95/21627, Lumsden et al (Am. J. Vet. Res., 1991, 52/11:1784-1787) taken with Tabaraie et al (Microbiol. Immunol., 1994, 38/7:553-559).

Emery et al teaches a vaccine for immunizing poultry (i.e. avian) and other animals against infection by gram-negative bacteria and that the vaccine comprises isolated SRPs from gram-negative bacteria, isolated porins from gram-negative bacteria and a physiologically acceptable carrier (abstract; p. 2; Example 16, p. 47; p. 7). Emery et al teaches that the SRPs have a molecular weight of 72-96 kD (p. 3; pp. 8-10). Emery et al also teaches that the composition comprises isolated porins from gram-negative bacteria having a molecular weight of 34-38 kD (p. 14). Emery et al set forth various gram-negative bacteria suitable for use in obtaining SRPs (p. 17).

Lumsden et al is cited to show that animals vaccinated with vaccines comprising gram-negative bacteria (i.e. *Salmonella spp.*) shed Salmonella less frequently than nonvaccinated control animals (summary). The vaccine prevented fecal shedding of microbes (p. 1784).

The prior art teaches the claimed invention except for specifically stating that the vaccine contains the component LPS.

However, Tabaraie et al teaches porins prepared from gram-negative bacteria (Salmonella) and that these porins can protect against salmonellosis in mice (abstract; Table 3; Table 4; Table 5). Tabaraie et al teaches the purification of porins, but that there were LPS contaminants in the porin preparations that were

less than 0.5% of the porin preparation (p. 555, column 2). The LPS concentration was 0.02 ng/ml (Table 1). This concentration is less than the 10.0 EU/ml set forth in the pending claims. It is noted that the specification indicates that 1 nanogram of pure LPS is equal to 5-10 endotoxin units (EU) (see p. 15). Tabaraie et al teaches that the superiority of the semipurified porins in the protection may be because of the host responses to the contaminants, including LPS (p. 558, column 1).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the composition (SRP and porins) as taught in Emery et al to protect against salmonellosis by reducing the fecal shedding of gram negative microbes (concept shown by Lumsden et al) in the animal's intestinal tract since the prior art of Tabaraie et al teaches that porin preparations are contaminated with LPS. Both Emery et al and Tabaraie et al teach that porins can be used to protect against gram-negative microbes. It would have been obvious to a person of ordinary skill in the art at the time the invention was made that in view of the teachings of Tabaraie et al regarding LPS contamination in the porin preparation that porin preparation taught in Emery et al would be contaminated with LPS as well. The claimed invention is prima facie obvious in view of the combined teachings of the prior art, absent any convincing evidence to the contrary.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See

In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 30 and 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5830479 in light of Lumsden et al or claims 1-16 of U.S. Patent No. 6027736 in light of Lumsden et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and patents claim and disclose compositions comprising at least two siderophore receptor proteins, SRPs, (MW of 60-100 kD) from a gram negative microbe, at least two porins (MW of 30-43 kD) from a gram-negative microbe and a pharmaceutically acceptable carrier for use in a method for immunizing an animal (avian, bovine, caprine, porcine or ovine).

Emery et al (for example 5830479) discloses a vaccine for immunizing poultry (i.e. avian) and other animals against infection by gram-negative bacteria and that the vaccine comprises isolated SRPs from gram-negative bacteria, isolated

porins from gram-negative bacteria and a physiologically acceptable carrier (abstract; claims; col. 1; col. 11). Emery et al discloses that the SRPs have a molecular weight of 72-96 kD (col. 2; claims; col. 8). Emery et al also discloses that the composition comprises isolated porins from gram-negative bacteria having a molecular weight of 34-38 kD (col. 7; claims). Emery et al set forth various gram-negative bacteria suitable for use in obtaining SRPs (col. 9).

Lumsden et al is cited to show that animals vaccinated with vaccines comprising gram-negative bacteria (i.e. *Salmonella spp.*) shed Salmonella less frequently than nonvaccinated control animals (summary). The vaccine prevented fecal shedding of microbes (p. 1784).

The prior art of Emery et al appears to disclose the claimed method of administering the claimed composition (SRPs, porins and physiologically acceptable carrier) to an animal. Although the prior art is silent with regard to LPS to claim recites that the composition has a concentration no greater that 10 EU/ml, therefore a composition that has no LPS would meet that limitation. Further, with regard to the recitation of "for reducing fecal shedding of a microbe in an animal's intestinal tract", this is viewed as a recitation of the intended use. The recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In light of Lumsden it would appear that the

vaccine composition of Emery et al would be useful to reduce fecal shedding of a microbe.

This rejection is maintained for the reasons of record. Applicants' arguments filed October 20, 2003, have been fully considered but they are not deemed to be persuasive. Applicants have argued that the US Patents (5830479 or 6027736) do not suggest the claimed invention, and no convincing line of reasoning has been presented. It is noted that Applicants have not set forth any arguments regarding the double patenting rejection.

13. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

14. Claims 30-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 30-38 of copending Application No. 10/454306. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

15. Claims 30-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 30-38 of copending Application No. 10/454305. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394 (571-272-0860). The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909 (571-272-0864). The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

January 14, 2004